

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicant: ROZALINA DIMITROVA, et al.)	Examiner:
Serial Number: Pending )	Art Unit:
Filed: Herewith )	Confirmation No.
For: BOTULINUM TOXIN INJECTION )	
<u>GUIDE</u> )	Irvine, California

**INFORMATION DISCLOSURE STATEMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Dear Sir:

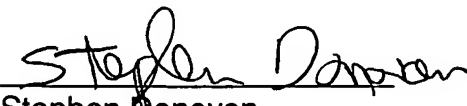
Applicant's provide with regard to the patent application entitled BOTULINUM TOXIN INJECTION GUIDE, filed herewith one copy of a documents of which they are aware, which may be material to the examination of this application, and in respect of which there may be a duty of disclosure under 37 C.F.R. §1.56. A listing of documents submitted is set forth on the attached Information Disclosure Citation (Form PTO-1449).

While these documents may be material pursuant to 37 C.F.R. §1.56, their disclosure is not intended to constitute an admission that the documents are prior art in regard to this invention. The filing of this Statement should not be construed to mean that a search has been conducted or that no other material documents or information exists. Please do not hesitate to contact the undersigned should any questions arise regarding this Statement.

The Commissioner is hereby authorized to charge any fees required or necessary for the filing, processing or entering of this paper or any of the enclosed papers, and to refund any overpayment, to deposit account 01-0885.

Respectfully submitted,

Date: December 29, 2003

  
Stephen Donovan  
Registration Number 33,433

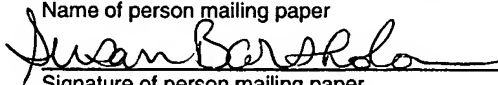
Please direct all inquiries and correspondence to:

Stephen Donovan  
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2525 Dupont Drive, T2-7H  
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**CERTIFICATE OF EXPRESS MAIL UNDER 37 C.F.R. § 1.10**

I hereby certify that this Information Disclosure Statement and the documents referred to as enclosed herein are being deposited with the United States Postal Service on this date December 29, 2003, in an envelope as "Express Mail Post Office to Addressee" Mailing Label number EV295682673US addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Date: December 29, 2003

Susan Bartholomew  
Name of person mailing paper  
  
Signature of person mailing paper

### LIST OF ART CITED BY APPLICANT

ATTY. DOCKET: 17638 (BOT)	SERIAL NO.: PENDING
APPLICANT DIMITROVA, ET AL..	TITLE: BOTULINUM TOXIN INJECTION GUIDE
FILING DATE: HEREWITH	GROUP

### U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NO.	DATE	NAME	CLASS	SUB-CLASS	FILING DATE (if applicable)
	AA	10/621,054	7/15/03	Caers, et al.			July 15, 2003
	AB	5,437,291	8/1/1995	Pasricha et al.			
	AC	5,670,484	9/23/1997	Binder			
	AD	5,714,468	2/3/1998	Binder			
	AE	5,766,605	6/16/1998	Sanders et al.			
	AF	6,063,768	5/16/2000	First			
	AG	6,063,768	5/16/2000	First			
	AH	6,113,915	9/5/2000	Aoki et al.			
	AI	6,139,845	10/31/2000	Donovan			
	AJ	6,143,306	11/7/2000	Donovan			
	AK	6,265,379	7/24/2001	Donovan			
	AL	6,299,893	10/9/2001	Schwartz et al.			
	AM	6,306,403	10/23/2001	Donovan			
	AN	6,306,423	10/23/2001	Donovan et al.			
	AO	6,312,708	11/6/2001	Donovan			
	AP	6,328,977	12/11/2001	Donovan			
	AQ	6,358,513	3/19/2002	Voet et al.			
	AR	6,365,164	4/2/2002	Schmidt			
	AS	6,395,277	5/28/2002	Graham			
	AT	6,423,319	7/23/2002	Brooks et al.			
	AU	6,458,365	10/1/2002	Aoki et al.			
	AV	6,464,986	10/15/2002	Aoki et al.			

### FOREIGN PATENT DOCUMENTS

		DOCUMENT NO.	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION (yes/n )
	BA						

### OTHER ART

(Including Author, Title, Date, Pertinent Pages, etc.)

	CA	Aoki K.R., <i>Pharmacology and immunology of botulinum toxin serotypes</i> , J Neurol 248(suppl 1);1/3 -1/10:2001
	CB	Aoki KR, Cui M, <i>Mechanisms of the Antinociceptive Effect of Subcutaneous BOTOX®: Inhibition of Peripheral and Central Nociceptive Processing</i> , Cephalalgia 23(7);649:2003

EXAMINER \_\_\_\_\_ DATE CONSIDERED \_\_\_\_\_

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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<b>ATTY. DOCKET:</b> 17638 (BOT)	<b>SERIAL NO.:</b> PENDING
<b>APPLICANT</b> DIMITROVA, ET AL..	<b>TITLE:</b> BOTULINUM TOXIN INJECTION GUIDE
<b>FILING DATE:</b> HEREWITH	<b>GROUP</b>

	CC	Argoff, <i>A Focused Review on the Use of Botulinum Toxins for Neuropathic Pain</i> , Clin J Pain 18(6 Suppl);S177-S181:2002
	CD	Bigalke H., et al., <i>Botulinum A Neurotoxin Inhibits Non-Cholinergic Synaptic Transmission in Mouse Spinal Cord Neurons in Culture</i> , Brain Research 360;318-324:1985
	CE	Bigalke H., et al., <i>Tetanus Toxin and Botulinum A Toxin Inhibit Release and Uptake of Various Transmitters, as Studied with Particulate Preparations From Rat Brain and Spinal Cord</i> , Naunyn-Schmiedeberg's Arch Pharmacol 316;244-251:1981
	CF	Binz T. et al., <i>The Complete Sequence of Botulinum Neurotoxin Type A and Comparison with Other Clostridial Neurotoxins</i> , J Biological Chemistry 265(16);9153-9158:1990
	CG	Bushara K., <i>Botulinum toxin and rhinorrhea</i> , Otolaryngol Head Neck Surg 1996;114(3):507
	CH	Cui M, Aoki KR, <i>Botulinum toxin type a (BTX-a) reduced inflammatory pain in the rat formalin model</i> , Cephalalgia 20(4);414:2000
	CI	Cui M, Li Z, You S, Khanijou S, Aoki KR, <i>Mechanisms of Antinociceptive Effect of Subcutaneous BOTOX® : Inhibition of Peripheral and Central Nociceptive Processing</i> , Naunyn Schmiedegergs Arch Pharmacol 265(Suppl 2);R17:2002
	CJ	Duggan, J.J., et al., <i>Mov Disord</i> , 10(3):376:1995
	CK	Durham P, Cady R, Cady R, <i>Mechanism of botulinum toxin type-A Inhibition of Calcitonin Gene-Related Peptide Secretion from Trigeminal Nerve Cells</i> , Cephalalgia 23(7);690:2003
	CL	Gonelle-Gispert, C., et al., <i>SNAP-25a and -25b isoforms are both expressed in insulin-secreting cells and can function in insulin secretion</i> , Biochem J 1;339 (pt 1): 159-65:1999
	CM	Grimalt, R., <i>Multi-injection plate for botulinum toxin application in the treatment of axillary hyperhidrosis</i> , Dermatol Surg 2001 Jun;27(6): 543-544
	CN	Habermann E., <i>Inhibition by Tetanus and Botulinum A Toxin of the release of [<sup>3</sup>H]Noradrenaline and [<sup>3</sup>H]GABA From Rat Brain Homogenate</i> , Experientia 44;224-226:1988
	CO	Habermann, E., et al., <i>Tetanus Toxin and Botulinum A and C Neurotoxins Inhibit Noradrenaline Release From Cultured Mouse Brain</i> , J Neurochem 51(2);522-527:1988)
	CP	Habermann, <i>Naunyn-Schmiedeberg's Arch. Pharmacol.</i> 1974; 281, 47-56
	CQ	Jankovic J. et al., <i>Therapy With Botulinum Toxin</i> , Marcel Dekker, Inc., (1994), page 5
	CR	Marchese-Ragona, R., et al., <i>Management of parotid sialoceles with botulinum toxin</i> , The Laryngoscope, Aug. 109(8):1344-1346:1999
	CS	Moyer, et al., <i>Botulinum toxin type B: experimental and clinical experience</i> , Ch. 6, pgs. 71-85, <i>Therapy with Botulinum Toxin</i> , ed. Jankovic, J., et al. (1994) Marcel Dekker, Inc.
	CT	Naumann, M., et al., <i>Botulinum toxin type A in the treatment of focal, axillary and palmar hyperhidrosis and other hyperhidrotic conditions</i> , European J. Neurology 6 (Supp 4): S111-S1150:1999
	CU	Pearce, L.B., <i>Pharmacologic Characterization of Botulinum Toxin For Basic Science and Medicine</i> , Toxicon 35(9);1373-1412 at 1393
	CV	Sanchez-Prieto, J., et al., <i>Botulinum Toxin A Blocks Glutamate Exocytosis From Guinea Pig Cerebral Cortical Synaptosomes</i> , Eur J. Biochem 165;675-681:1987

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	CW	Shantz, E.J., et al, <i>Properties and use of Botulinum toxin and Other Microbial Neurotoxins in Medicine</i> , Microbiol Rev. 56;80-99:1992
	CX	Singh, B.R., et al. <i>Critical aspects of bacterial protein toxins</i> , Natural Toxins II, Ch. 4, edited by B.R. Singh, et al., Plenum Press, New York (1976), pgs. 63-84
	CY	Sloop, R.R., et al., <i>Reconstituted botulinum toxin type A dose not lose potency I humans if it is refrozen or refrigerated for 2 weeks before use.</i> , Neurology, 48:249-53:1997
	CZ	Weigand et al, <i>Nauny-Schmiedeberg's Arch. Pharmacol.</i> 1976; 292, 161-165

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